

REMARKS

Applicant respectfully traverses the rejection of Claims 16 – 24 of the above-identified application. In applicant's opinion the subject matter of claims 16 – 24 is not rendered obvious by the combination of the three cited references, namely Published US application 200330064104 (*Stillman*), United States Patent No. 5,567,424 (*Hastings*) and United States Patent No. 6,159,491 (*Durrani*). The reasons are as follows.

At the very outset applicant responds that much of the discussion of the grounds of the rejection in the last Office Action is directed to claims which are not in issue, because they have been canceled. These canceled claims were drawn to a dietary supplement (composition of matter). The presently pending claims are method claims. Specifically, in page 4, first paragraph of the Office Action the Examiner states that the subject matter of Claim 8 is obvious over the teachings of the *Stillman* reference. Applicant does not concede that this is the case, but applicant is of the view that this holding is irrelevant to the patentability of the instant method claims. In page 5, last paragraph of the Office Action the Examiner states that Claims 2, 4 and 6 are obvious in light of the *Hastings* reference. Again, applicant does not concede that this is the case, but applicant is of the view that this holding is irrelevant to the patentability of the instant method claims.

It is elementary and well settled patent law, that each patent claims must be considered on its own. Therefore, the instant method claims must be considered as such and not on the basis of the composition of matter claims that are not pending.

In the previous Office Action the Examiner considered method claims 23 and 24 allowable if re-written in independent format. (This was done in applicant's response to the previous Office Action.) Before they were

amended to become independent both of those claims were originally dependent from method Claim 16. Original dependent Claim 23 merely added the requirement that see weed and psyllium are not admixed before administration to human or domestic animal. Original dependent Claim 24 merely added the requirement that these two components are admixed before administration to human or domestic animal. Both of these original claims (initially considered by the Examiner to be allowable) used in the claimed method the same ingredients and in the same amounts as in present Claim 16. Applicant's comment in applicant's response to the previous Office Action that

“-----in light of the clear allowability of Claims 23 and 24 over all known prior art there is no logical reason that method claims 16 – 22 are in any way would be rendered anticipated or obvious by the known prior art. “

made sense in the previous response and is maintained presently. Claims 16 itself is patentable because it describes an unobvious method. It appears that the Examiner considered this comment as grounds for rejecting all method claims including Claims 23 and 24 in their independent form. Applicant respectfully submits that this action by the Examiner is in serious error. If the Examiner disagrees with the conclusion that Claim 16 is patentable then that is still not sufficient reason to also to hold Claims 23 and 24 obvious and unpatentable.

The cited *Stillman* reference teaches a shelf-stable, ready to use *water-like composition* for humans and animals (see Abstract of the reference). A principal component of the *Stillman* composition is soluble fiber. Nowhere does the *Stillman* reference teach or even imply that using the

Stillman composition would result in minimizing, after bowel movement, the amount of residual fecal matter in the perianal area of the human or of the domestic animal. In fact, a water-like composition is highly unlikely to have that result in spite of the presence of soluble-fiber in it.

The *Hastings* reference is also directed to a beverage composition, and nowhere describes the result attained in the present invention, nor does the *Hastings* reference set that out as a purpose. It is true that *Hastings* mentions carrageen (seaweed) but it is in such a low dose that it would be fairly ineffective in achieving perianal cleanliness when combined with psyllium. *Hasting's* range of 100 to 500 mg is only theoretically possible to have any effect on the smallest animals or children in imparting the important rheologic properties that allow for a clean separation of fecal matter from the anus. His preferred amount to use is only 0.12 grams. The study in connection with the present invention included children to seniors and utilized 580 grams of carrageen and was administered in conjunction with psyllium. The range of seaweed recited in the instant claims is to provide for the use of the combination of seaweed with psyllium to bring about the desired result from tiny of animals to normal or even large sized humans.

The *Durrani*. reference "teaches" Irish moss as a bulk laxative (see column 8, line 62 *et seq.*). There is no mention to "suggest that a formulation comprising dried seaweed "may" have additive/synergistic effects in conjunction with psyllium" at the location of the anus. And, even if it did, it doesn't imply what those "effects" might be or have any relation to the rheologic effects needed to impart the characteristics to lead to clean separation of fecal matter from the perianal area. Also the *Durrani* reference teaches about the absorptive effects for a vaginal application that has nothing

to do with the rheologic properties that concerns the present invention specifically for the perianal area.

It should be noted that unlike the composition of the *Hastings* reference the composition used in the present method is not a beverage. More likely it is administered in a capsule (see the instant specification, *inter alia* on page 4 last paragraph to page 5 last paragraph) although some of the psyllium may be administered while admixed with water to avoid inhalation of light dust (see the page 5 second paragraph of the specification).

The fact that the Examiner needed to combine three references to hold the presently claimed invention obvious is itself a strong indication that the invention is not obvious. None of the references describe or suggest the purpose of the present invention (to keep the perianal area clean from fecal matter) and there would have been absolutely no reason for a person of ordinary skill in the art to combine them for this or any other purpose.

Applicant also notes that to applicants' best knowledge no internal (oral ,i.e., systemic) product has ever been designed for the use of the present invention and no one has apparently ever mentioned this specific use for any product on the market. Since the impact of such a product and method could have huge economic, environmental, social and health benefits, by reducing the need for and use of toilet paper, the presently claimed method is clearly not obvious. If it were obvious it would have been mentioned somewhere in association with a product or patent since the financial rewards could be significant.

For all of the foregoing reasons allowance of all outstanding claims of the present application is respectfully solicited.

In the event the Examiner is of the opinion that a telephone conference with the undersigned attorney would materially facilitate the final disposition of this case, he is respectfully requested to telephone the undersigned attorney at the below listed telephone number.

Respectfully submitted

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